

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

Oral Argument Requested

**MEMORANDUM OF LAW IN SUPPORT OF  
DEFENDANTS' MOTION TO EXCLUDE  
OPINIONS OF ZIRUI SONG, M.D., PH.D**

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Pursuant to Federal Rules of Evidence 702 and 703, Defendants' Executive Committee, on behalf of the undersigned Defendants, respectfully submits this Memorandum of Law in Support of Defendants' Joint Motion to Exclude Opinions of Dr. Zirui Song ("Motion").

## INTRODUCTION

Dr. Zirui Song is a medical doctor and economist who purports to set forth a "common methodology" for determining the healthcare spending that would accrue from Plaintiffs' proposed medical monitoring program. Dr. Song opines that to determine medical monitoring spending, he would multiply the prices for healthcare services by the quantity of services to be provided (*i.e.*, price x quantity = spending). While Dr. Song's formula is simplistic by design, both factors in his superficial equation are riddled with fundamental methodological problems, rendering his opinions irrelevant and inadmissible.

**First**, with respect to price, Dr. Song fails to address (much less reliably account for) the myriad variations in healthcare pricing that are implicated by the unprecedented scope of Plaintiffs' proposed medical monitoring classes. Although these variations are serious obstacles to any common methodology seeking to estimate spending, Dr. Song largely ignores them. Rather than identify a method to account for genuine pricing variability (if any such method exists), Dr. Song's estimates rest on Medicare pricing as a proxy for all healthcare spending, and then

applies grossly oversimplified ratios to adjust Medicare pricing to other market conditions without accounting at all for the actual makeup of the putative class populations. For example, Dr. Song opines that commercial insurance prices for physician services are, on average, 43% higher than Medicare prices for the same service. Dr. Song then attempts to extrapolate that a ratio of 1.43 can be applied to determine the commercial price of any medical service—irrespective of the type of service or where it was performed. The study that is the crux of Dr. Song’s opinion, however, involved a different population of patients than the older one encompassing Plaintiffs’ proposed medical monitoring classes here. Indeed, additional literature—which Dr. Song failed to consider—makes clear that there is wide variation in commercial healthcare pricing, which is impacted by such disparate factors as geography, provider purchasing power, cost sharing, and insurance coverage. In short, Dr. Song’s methodology is unreliable and should be excluded.

***Second***, Dr. Song’s approach to quantities of services—the other half of his so-called “common methodology”—separately demonstrates that his opinions do not “fit” the facts of this case and would therefore not assist the jury or the Court in determining the cost of Plaintiffs’ medical monitoring program. Dr. Song makes no attempt to define (i) who will be included in the medical monitoring program, (ii) the services to be provided in the program, or (iii) the duration of the program. As a

result, Dr. Song cannot even provide an estimate of how much Plaintiffs' proposed medical monitoring program will ultimately cost. Instead, he attempts to leave that fundamental exercise for another day, when some as-yet-unidentified person defines the quantities of services necessitated by the proposed monitoring program. As a result, Dr. Song's "common methodology" amounts to nothing more than an untested hypothesis that cannot assist the Court in determining whether a medical monitoring class should be certified.

For these reasons, the Court should exclude Dr. Song's opinions in their entirety, including the following:

- "U.S. commercial insurer prices for physician services are 43% higher (a ratio of 1.43), on average, compared to Medicare prices for the same service." Ex. A, Expert Report of Zirui Song ("Song Rep.") ¶ 22, Nov. 10, 2021.
- "U.S. commercial insurer prices for hospital outpatient services . . . are on average 164% higher (a ratio of 2.64) than Medicare prices." *Id.* ¶ 22.
- "In the class of patients in this case, the presumptive spending on a medical monitoring program can be calculated as the prices of health care services multiplied by the quantities of services determined to be in the monitoring program, applied to a population of people with a given health insurance mix, shares of services obtained at different sites of care, and shares of services delivered by in-network vs. out-of-network providers." *Id.* ¶ 42.
- "Such a methodology would also be able to incorporate factors such as the expected number of years in the monitoring program, and rate of attrition from the monitoring program, and the contribution of market forces such as price inflation due to provider consolidation. Additional factors that affect prices or quantities of care may also be incorporated." *Id.* ¶ 42.

## BACKGROUND

Dr. Song offers a narrow opinion: that there is a “common methodology” for calculating medical monitoring spending (price x quantity = spending). *Id.* ¶ 22. Dr. Song’s opinion focuses on the “price” side of his equation—albeit with calculated ambiguity—while deliberately leaving the “quantity” value unknown.

With respect to price, Dr. Song relies on a set of assumptions, which includes the use of Medicare pricing as a proxy for commercial insurance pricing. *Id.* ¶ 22. In particular, Dr. Song opines that “U.S. commercial insurer prices for physician services are 43% higher (a ratio of 1.43), on average, compared to Medicare prices for the same service.” *Id.* He further opines that “U.S. commercial insurer prices for hospital outpatient services . . . are on average 164% higher (a ratio of 2.64) than Medicare prices.” *Id.* Notably, these ratios are derived from a single meta-analysis.<sup>1</sup> That meta-analysis combined the results from 19 individual studies, which relied upon data from 2010-2017, and yielded an average ratio between Medicare and commercial pricing of 1.43, which Dr. Song blindly adopts. Ex. B, Deposition of Zirui Song (“Song Dep.”) 244:20-24, Feb. 8, 2022. The individual studies, however,

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<sup>1</sup> See *E. Lopez, et al.*, “How Much More Than Medicare Do Private Insurers Pay? A Review of the Literature,” Kaiser Family Foundation Issue Brief, April 15, 2020 (<https://www.kff.org/report-section/how-much-more-than-medicaredo-private-insurers-pay-a-review-of-the-literature-issue-brief/>) (hereinafter, “*Lopez*” or the “*Lopez* study”).



contained a range of prices, with some finding the ratio to be greater than 1.43, and others finding it to be smaller. *Id.* 232:22-235:2.

Notably, Dr. Song adopted the general, retrospective ratios from the meta-analysis without any attempt to adjust for the population of the putative classes, changes in the healthcare market since 2010 (*e.g.* the implementation of the Affordable Care Act in 2014), or acknowledged variations and fluctuations in pricing across the healthcare marketplace. For example, Dr. Song concedes that “just like the economy for a gallon of gasoline, there are price differences, and price variations” based on, among other factors, “geography” and “differences in market power” in different areas. *Id.* 234:5-10. Such geographic differences are directly relevant here, as Plaintiffs’ putative Medical Monitoring Independent Claim Class comprises residents of 27 listed states and the District of Columbia, and even Plaintiffs’ Medical Monitoring Remedy Class excludes one state (Mississippi). (Dkt. 1747-3). Yet, Dr. Song ignores geographic variation entirely and simply adopts the “national average of the ratio[] of average commercial prices to average Medicare prices” across all geographic regions, and his model would apply that national average ratio to every putative class member in every state. *Id.* 234:14-25. Similarly, for Medicaid prices, Dr. Song conceded “[t]here is empirical evidence that Medicaid prices differ state to state,” yet he adopted a single ratio to convert from Medicare prices to Medicaid prices across all states. *Id.* 240:2-242:9.

These are not the only differences in pricing data that Dr. Song ignores. He also acknowledges that the 19 individual studies incorporated into the meta-analysis contain “differences in the datasets and the years of data that are used, and therefore, there are differences in the samples of medical services used to construct those studies,” which he could not “reconstruct . . . from memory” at his deposition. *Id.* 234:7-17. He makes no effort to identify which studies involved services like those proposed for the putative medical monitoring classes and no attempt to derive a pricing ratio adjusted for the putative class population. Rather, he simply recites that “at least some of the six illustrative services” also “do exist in a number of these studies,” and then adopts the bottom-line “central tendency” number as his one-size-fits-all ratio for commercial services. *Id.* 235:25-236:6.

As for the other half of his proffered equation, Dr. Song does not define the quantity of services that would be applied in his formula, which consist of (i) who would be included in the medical monitoring classes, and (ii) the services that would be provided in the medical monitoring program.<sup>2</sup> Dr. Song admitted he was not

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<sup>2</sup> Although it is unclear in his report, Dr. Song confirmed at his deposition that defining the particular services to be included in the medical monitoring plan was beyond the scope of his assignment in this case, and possibly outside of his expertise. Song Dep. 72:13-73:22. Dr. Song deferred to Dr. Edward Kaplan, one of Plaintiffs’ other class certification experts, about the composition of the medical monitoring regimen. *Id.* 77:23-78:11. Defendants have moved separately to exclude Dr. Kaplan’s opinions. *See* Defendants’ Mot. To Excl. Op. of Edward H. Kaplan, M.D. (Dkt. 2024).

“asked to make a determination about the elements of quantity, such as the services in the monitoring program, who is in the monitoring program, [or] the duration of the monitoring program.” Song Dep. 253:19-23. Because he never determines the quantity of services to be included, Dr. Song does not apply or attempt to apply his formula to estimate total medical monitoring spending. *See, e.g., Id.* 258:20-25 (“[I]t’s a fairly narrow task that I was retained to conduct, and there are lots of important questions around class membership and definition in the monitoring program components itself that we talked about at length today, which frankly is outside the scope of this report[.]”). Further, although he recognizes that “additional factors that affect prices and quantities of care” (*e.g.*, individual patient variance) could hypothetically be factored into his formula, he never explains how that would be done. Instead, Dr. Song lists six “illustrative examples of a set of services that could comprise the start or the foundation of [a] potential medical monitoring program.”<sup>3</sup> *Id.* 105:13-17. Dr. Song is careful to specify that “those examples are meant to be illustrative rather than as a recommendation or as a framework for the final screening program, which again, has not yet been determined or certified.” *Id.*

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<sup>3</sup> The six “illustrative” services suggested by Dr. Song—which differ in some respects from those recommended by Dr. Kaplan—include “a urinalysis on an annual basis, a complete blood count on an annual basis, an evaluation and management (office visit) on an annual basis, a low-dose computed tomography (CT) chest imaging test on an annual basis, an upper endoscopy every five years, and a screening colonoscopy every five years.” Song Rep. ¶ 32.

105:18-21.

Dr. Song then tries to demonstrate how his “common methodology” could be applied by multiplying price (based on his Medicare to Medicaid/commercial insurance ratios) times quantity (the six illustrative services) for a single hypothetical class member at a fixed moment in time. Song Rep. ¶¶ 32-38. But he concedes that in order to apply his formula to calculate total spending on the medical monitoring program for all class members over time, the “next step” would be to:

determine or estimate the size and composition of the patient population undergoing monitoring. This includes determining the insurer mix, site of care composition, and network status of the providers for the patient population. In addition, projecting future health care use requires assumptions about life expectancy and the development of medical conditions (e.g. cancer and other acute and chronic diseases) that may render the monitoring program less appropriate clinically.

*Id.* ¶ 39. But Dr. Song never undertakes this “next step.” Tellingly, he does not even believe it would be possible to do so at this juncture:

A. You need to know what tests are certified as part of the monitoring program and how frequently they are to be administered and what the size of the certified class ends up being.

\* \* \*

A. We have talked about this earlier today, and this is well outside the scope of what I’m opining on in this report, and I would refer you to the oncologist expert for that question.

Q. Okay, so we should ask the oncologist what percentage of time a given test is appropriate for a given patient for a given cancer?

MR. MIGLIACCIO: Same objection. You can answer.

A. I think that's well within the confines with our earlier discussion and with your colleague where we talked about the elements of the quantities in the medical monitoring program being defined by others in this case outside of what I'm doing on the pricing of medical services.

Song Dep. 283:2-5; 284:14-24.

Dr. Song went on to further concede that, once all individuals to be included in the monitoring program have been identified, and the services to be provided have been defined, it would then be necessary to undertake a more rigorous analysis of the population to apply his model. Specifically, he acknowledged that projecting future healthcare use finalizing the “quantity” factor in his equation for the selected patient population would require evaluating, among other factors, “insurance mix,” “life expectancy,” and “development of medical conditions (*e.g.*, cancer and other acute and chronic diseases) that may render the monitoring program less appropriate clinically.” Song Dep. 264:2-266:22. Dr. Song acknowledged the “factfinder” would “likely take these considerations into account in determining the final monitoring program” and in determining quantity under his formula, and suggested that “one way” to “go about determining” these considerations “might be to ask the class members”—that is, inquiring individually of each class member regarding their insurance status and coverage, their medical history, and their risk factors. *Id.* 266:23-269:2. Thus, the ultimate application of Dr. Song’s methodology with respect to the quantity factor—the side of the equation he did not analyze—entails

an individualized inquiry into each class member’s insurance, medical history, and risk factors. And even then, Dr. Song recognized the “final decisionmaker” for a given patient’s “quantity” of medical services could include (and should include) the “individual physician” and should account for “the potential role of patient and provider preferences[.]” *Id.* 272:15-275:7.

Moreover, Dr. Song indicates that his example only applies to the “initial years” of the monitoring program. He acknowledges that “[o]ver longer time horizons,” other factors and assumptions would need to be considered including, among others, life expectancy, market forces, and insurance switching among class members. Song Rep. ¶ 41; *see also id.* ¶ 42 (acknowledging “factors such as the expected number of years in the monitoring program, and rate of attrition from the monitoring program, and the contribution of market forces such as price inflation due to provider consolidation.”). Dr. Song, however, does not indicate how these variations would be factored into his “common methodology” to estimate total spending, either before or after a class is certified.

### **LEGAL STANDARD**

The standards governing the admissibility of expert testimony at the class certification stage of litigation are set forth in Defendants’ Memorandum of Law in Support of Motion to Exclude Opinions of Dr. Edward H. Kaplan, M.D. (Dkt. 2024), and are incorporated fully herein.

## ARGUMENT

### I. DR. SONG'S ANALYSIS OF HEALTHCARE PRICING AND QUANTITY IS OVERLY SIMPLISTIC AND PREDICATED ON FLAWED ASSUMPTIONS.

The Court should exclude Dr. Song's purportedly common methodology for calculating the cost of Plaintiffs' proposed medical monitoring program because it ignores the complex and disparate nature of healthcare pricing in the United States.

Consistent with the general principle that every step of an expert's methodology must be reliable, *see In re Zolof (Sertraline Hydrochloride) Products Liability Litigation*, 858 F.3d 787, 797 (3d Cir. 2017), opinions regarding damages are not admissible if they are based on "unsupported and speculative" assumptions. *Williams v. Rene*, 72 F.3d 1096, 1102 (3d Cir. 1995) (actuarial expert cannot opine that plaintiff's gross earnings would triple during the remainder of career where "the record contains no data on the salary scales at the Water and Power Authority and nothing to indicate that the plaintiff's experience and training would qualify him for positions higher than the one he held at time of trial"); *see also, e.g., Lithuanian Commerce Corp. v. Sara Lee Hosiery*, 179 F.R.D. 450, 460 (D.N.J. 1998) (excluding testimony from damages expert because it was based on "inadequate foundation"); *Frost v. Taco Barge Line, Inc.*, No. 04-cv-752-DRH, 2007 WL 518634, at \*5 (S.D. Ill. Feb. 15, 2007) (excluding opinions that "were based upon a flawed assumption").

Dr. Song's opinions should be excluded under this principle because they are

based on a fundamentally flawed premise—that the price of healthcare in the United States is static and uniform across the country. In his report, Dr. Song recognizes that the price of healthcare services varies both **between** and **within** insurers, depending on a patient’s plan, the location of the provider, the type of facility providing the service, and whether the provider is in or out of network. Song Rep. ¶ 31. Dr. Song nevertheless attempts to paper over these undisputed variations in commercial insurance pricing by assuming that Medicare prices—which are set by the federal government—can be used as a proxy to measure commercial insurance prices. But, as Defendants’ expert Dr. David Chan—a physician and professor of economics at Stanford University—has explained, Dr. Song’s assumption is not methodologically sound because “variation in private insurance prices is the major source of variation in healthcare spending under private insurance, in contrast with variation in spending under Medicare which is driven by quantity variation.” Ex. C, Expert Report of Dr. David Chan (“Chan Rep.”), ¶ 108, Jan. 12, 2022.

Dr. Song relies on a single meta-analysis, the *Lopez* study, that aggregated individual studies and found that, **on average**, private insurance paid 143% of Medicare rates for physician services and 264% of Medicare rates for hospital services. [cite to Lopez] His dependence on this study is misplaced and highly unreliable for multiple reasons. First, the *Lopez* study does not suggest—much less purport to find—that the price of commercial insurance can be measured by a simple



comparison to Medicare prices. To the contrary, even a cursory review of that analysis demonstrates that “the magnitude of the difference” between private and Medicare insurance prices varies “[a]cross all studies” and “may be due to a number of factors, including the representativeness of hospitals, physicians, and insurers used in the analysis, the data collection period, and the characteristics of the markets examined by each study[.]” *Lopez* at 2, 4 (“[P]rivate insurers’ payment rates are typically determined through negotiations with providers, and so vary depending on market conditions . . .”). Thus, the sole proffered basis for Dr. Song’s ratio-based approach to determining the price of medical monitoring services does not even support his purported methodology, demonstrating that his methodology is unreliable and inadmissible. *See In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449, 462 (E.D. Pa. 2014) (“opinion [was] based on subjective belief, rather than grounded in science” where “the studies [expert] does rely upon in her report do not adequately support her opinions”); *see also Jones v. U.S.*, 933 F. Supp. 894, 898 (N.D. Cal. 1996) (“us[ing] the data to reach a conclusion contrary to the articles’ own authors’” conclusions “does not qualify as good science.”).

Even assuming, *arguendo*, that the *Lopez* study could be utilized to support Dr. Song’s opinions, his reliance on it is still misplaced. As Dr. Chan explained at his deposition, the Medicare and private insurance prices at issue in the *Lopez* study pertained to a “population of patients that is almost certainly different than the

population of patients that we care about in this class”—who suffer from hypertension and tend to be older. Ex. D, Deposition of Dr. David Chan (“Chan Dep.”), 98:11-23, 195:11-17, March 3, 2022. Dr. Song failed to conduct the kind of rigorous analysis that would be necessary to bridge the “analytical gap,” *see General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997), between a single study identifying an average ratio of private commercial insurance prices to Medicare ones in one population, and his conclusion that such an average can be used to measure healthcare pricing for the millions of disparate individuals who would be included in the proposed medical monitoring classes. *See Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584 (D.N.J. 2002), *aff’d*, 68 F. App’x 356 (3d Cir. 2003) (excluding expert testimony where there were not “good grounds” for giving weight to studies involving chemicals other than PCE and to studies involving cancer other than leukemias, rendering “the body of evidence” relied upon was not “reliably composed.”).

Dr. Song’s singular focus on one meta-analysis, without analyzing other studies that undercut his opinion, is another telltale sign of an unreliable methodology. *In re Zolof*, 858 F.3d at 798 (district court properly raised the “concern that [expert] selectively used meta-analyses” where he ignored studies that did not support his position); *see also Daniels-Feasel Forest Pharms., Inc.*, No. 17 CV 4188-LTS-JLC, 2021 WL 4037820, \*8 (S.D.N.Y. Sept. 3, 2021) (excluding

opinions of expert who “repeatedly cherry-picks the findings on which he chooses to rely while disregarding the limitations expressed by the studies he cites in support of his conclusions, and dismisses inconsistent findings without explanation.”).

For example, a recent study analyzed by Dr. Chan (*Chernew, et al.*) that was neither considered by Dr. Song nor included in the *Lopez* study, “analyzed variation separately for inpatient facility, outpatient facility, and professional fees and found that the ratio of total commercial payments to counter traditional Medicare payments was higher for the two types of facility fees (2.06 [inpatient]; 2.16 [outpatient]) than professional fees (1.63).” Chan Rep. ¶ 109. Likewise, other studies have found that there is wide variation in pricing between major metropolitan areas. *Id.* (“A 2010 study of metropolitan healthcare markets in eight states found that average inpatient hospital payment rates of four large national commercial insurers ranged from 147 percent of Medicare to 210 percent of Medicare across markets.”). Another study analyzed 271 metropolitan areas across 48 states, “and found similarly high variation in commercial prices as a share of Medicare prices for professional services.” *Id.* Simply put, the geographical variation between commercial insurers in one location and those in another is so great that it cannot possibly be accounted for by a single meta-analysis purporting to average prices. Indeed, Dr. Song recognizes that this geographic variation exists, Song Rep. ¶ 23, but does not account for it.

Moreover, the variation among prices paid by different commercial insurers

is not limited to geography. To illustrate this point, Dr. Chan analyzed the outpatient prices that Dr. Song's employer, Massachusetts General Hospital ("MGH"), had negotiated with commercial insurers for the six illustrative medical monitoring services Dr. Song identified in his report. Chan Rep. ¶ 113. The following chart, reproduced from Dr. Chan's report, demonstrates the significant variation observed between different commercial insurers even within a single health system.

**Figure 8. MGH outpatient pricing for Professor Song's proposed procedures  
2021**

CPT/HCPCS Code	5th Percentile MGH Price Negotiated with an Insurer	95th Percentile MGH Price Negotiated with an Insurer	95th as % of 5th Percentile
81001 (Urinalysis)	\$10	\$44	429%
85025 (Complete blood count)	\$27	\$118	429%
99214 (30-39 minute office visit)	\$106	\$422	399%
71271 (Low-dose chest CT scan)	\$478	\$1,041	218%
43235 (Esophagogastroduodenoscopy)	\$482	\$2,069	429%
G0121 (Colonoscopy)	\$783	\$3,359	429%

**Notes:**

- [1] Analysis is limited to outpatient prices.
- [2] The MGH data record services according to MGH's procedure codes. For five of the above CPT/HCPCS codes, there is exactly one MGH procedure code associated with the code. However, in the case of CPT code 99214, MGH has three separate procedures associated with that CPT code. One of these MGH procedure codes is associated with psychiatric visits, so it is excluded from the analysis.

Source: MGH CMS-Required Hospital Charge Data (only includes commercial insurers), available at <https://www.massgeneral.org/notices/billing/CMS-required-hospital-charge-data>.

As depicted above, there is as much as a 429% variation between the lowest and the highest percentiles of prices charged by MGH for outpatient services for all of the monitoring services considered by Dr. Song. *See Id.* ¶ 113 ("[T]he 95th percentile price (i.e., the price that is higher than 95 percent of all prices negotiated) is 218 percent to 429 percent higher, or about 2 to 4 times higher, than the 5th percentile

price (i.e., the price that is higher than only 5 percent of all negotiated prices) charged by MGH . . .”). Given so much variation within a single health system, it is not surprising that there would be even more disparity across a wider geographical region. Indeed, this point is further exemplified by Dr. Chan’s analysis of OptumHealth data, which he segregated to include approximately 19,700 patients who purchased VCDs and underwent at least one of Dr. Song’s illustrative screening procedures during 2016.

**Figure 9. OptumHealth commercial pricing for Professor Song’s proposed procedures 2016**

CPT/HCPCS Code	No. of Patients	5th Percentile	25th Percentile	75th Percentile	95th Percentile	Median	Range 25th to 75th
81001 (Urinalysis)	3,851	\$1.30	\$2.41	\$6.00	\$28.80	\$3.00	\$3.59
85025 (Complete blood count)	8,453	\$3.06	\$5.51	\$17.00	\$57.00	\$7.82	\$11.49
99214 (30-39 minute office visit)	17,866	\$67.00	\$96.00	\$135.23	\$197.00	\$112.66	\$39.23
43235 (Esophagogastroduodenoscopy)	114	\$61.13	\$133.80	\$445.00	\$1,512.00	\$197.99	\$311.20
G0121 (Colonoscopy)	172	\$212.00	\$243.00	\$814.00	\$1,911.00	\$430.00	\$571.00

**Notes:**

- [1] Total price includes the deductible, copay, coinsurance, paid and coordination of benefits amounts for the respective procedures.
- [2] Patients were required to be under 65 years of age at the date of service, as patients who are 65 years old or older may have their medical benefits partially reimbursed by Medicare. Age was computed from July 1st of the birth year to the date of service.
- [3] Analysis includes inpatient (facility) and outpatient (non-facility) claims for services performed in 2016 for patients who took affected valsartan (see footnote 23) in 2012-2017. Professor Song only reports non-facility (outpatient) prices for the monitoring services that he identifies (Song Report, ¶38, Table 6).

Source: OptumHealth data.

As with the differences reflected in Figure 8, the price variations reflected in these data in Figure 9 are extensive, particularly for the more complex procedures like endoscopy and colonoscopy (both included in Dr. Kaplan’s proposed medical monitoring program), which vary as much as nine times from the lowest to the

highest percentile.

Accordingly, a single meta-analysis and a single ratio cannot even account for the price variation within a single health system like MGH, let alone across the entire United States and its territories. As a result, Dr. Song's reliance upon only the *Lopez* study to derive a single, global set of pricing ratios that he proposes to apply to all class members for both putative classes is unreliable, and the Court should exclude his pricing opinion based on this factor alone.

Dr. Song's methodology related to the "quantity" factor is even more problematic, as he simply does not perform the requisite analysis at all. As detailed in the Background section, *supra*, Dr. Song was not "asked to make," and did not make, "any determination about the elements of quantity, such as the services in the monitoring program, who is in the monitoring program, [or] the duration of the monitoring program." Song Dep. 253:19-23. He conceded these questions were "important," but were "outside the scope" of his analysis. *Id.* 258:20-25. He punted to someone else the determination of how to account for such critical factors as "insurance mix," "life expectancy," and "development of medical conditions (*e.g.*, cancer and other acute and chronic diseases) that may render the monitoring program less appropriate clinically," all of which he concedes are part of the "quantity" factor under his formula. *Id.* 264:2-266:22. And, confirming the unsuitability of his model for class-wide treatment, Dr. Song posits the "factfinder" might undertake to inquire

individually into each class member's insurance coverage, medical history, and risk factors in order to ascertain the "quantity" that would ultimately stand as the multiplier in his formula. *Id.* 266:23-269:2.

By his own admission, Dr. Song has abdicated his responsibility of supplying the Court with a reliable damages model it can rigorously assess at the class certification stage to determine whether the putative medical monitoring classes' damages can be determined by common, predominant evidence. A class certification expert cannot merely offer opinions that "could evolve to become admissible evidence" at trial. *In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 185-87 (3d Cir. 2015) (citing *Comcast v. Behrend*, 569 U.S. 27, 35-36 (2013)). At the class certification stage, this Court must "make a definitive determination that the requirements of Rule 23 have been met before certifying a class." *Id.* at 187 (quoting *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 320 (3d Cir. 2008)). A party's or expert's "assurance to the court that it intends or plans to meet the requirements is insufficient." *Id.* (quoting *In re Hydrogen Peroxide*, 552 F.3d at 318). The "rigorous" class certification analysis required by *Comcast* cannot be fulfilled by expert testimony that is "insufficiently reliable" to "prove" that the Rule 23(a) prerequisites have been met "in fact[.]" *Id.* at 187-88.

Here, it is impossible on the face of Dr. Song's model to undertake a "rigorous analysis" and to ascertain whether his simplistic "price times quantity" formula can

be applied to Plaintiffs’ proposed medical monitoring classes to calculate damages using common, classwide evidence. By Dr. Song’s own admission, his quantity analysis remains deliberately incomplete, leaving it to some future “factfinder” to decide (i) who belongs in the class—which may include individual inquiry to each class member, (ii) which procedures should be provided, and (iii) for what duration the monitoring should be provided. In short, Dr. Song’s method leaves the question of quantity entirely open-ended, and even invites individualized inquiry as the method to determine quantity. If the “factfinder” were to take Dr. Song up on that invitation, it is obvious that common evidence could not predominate to calculate damages. That is the rigorous analysis the Court must undertake now, yet Dr. Song has not supplied the method by which to do so. Accordingly, his opinion should be excluded.

**II. DR. SONG’S OPINIONS DO NOT “FIT” AND DO NOT ASSIST THE TRIER OF FACT BECAUSE HIS “COMMON METHODOLOGY” IS INCOMPLETE.**

Dr. Song’s opinions also do not “fit” because he did not finish the work he set out to do. In order to “fit,” expert testimony must “be “sufficiently tied to the facts of the case that it will aid” the” factfinder. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993) (citation omitted). This element “requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” *In re Pharmacy Benefit Managers Antitrust Litig.*, No. 06-1782 et al., 2017 WL 275398,



at \*17 (E.D. Pa. Jan. 18, 2017) (quoting *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F.App'x 781, 790 (3d Cir. 2009)).

The requisite fit is lacking where an expert proffers an opinion, but the completion of which will necessarily turn on future data to be applied at a later date. *See UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 835-36 (3d Cir. 2020) (district court erred in admitting damages testimony in bench trial by expert who acknowledged that he did not have all of the data to verify whether installation of a natural gas pipeline would reduce value of landowners' property). In such a case, the expert has offered “the beginning of a discussion and not the end,” meaning that the “testimony will not assist the trier of fact and [will] not fit the proceedings as the Federal Rules required.” *Id.* (quoting *In re TMI Litig.*, 193 F.3d 613, 670 (3d Cir. 1999) (affirming exclusion of expert testimony in part on fit grounds in case arising out of Three Mile Island accident where expert acknowledge that “I just don’t have enough of a database to prove details of this”)); *see also Ctr. City Periodontists, P.C. v. Dentsply Int’l, Inc.*, 321 F.R.D. 193 (E.D. Pa. 2017) (excluding damages expert where the class-wide damages model did not fit the facts of the case because it was premised on the incorrect assumption that the medical device at issue had “zero-value” despite expert stating he would modify the model to account for evidence of value if needed). But that is exactly what Dr. Song is offering here. As discussed above, Dr. Song acknowledges that he was not even

asked to compute the cost of a medical-monitoring program because the contours of the program are still inchoate, and the medical monitoring program has not been finalized. Song Dep. 253:19-254:5. As a result, Dr. Song is not able to ensure that his “common methodology” can be applied to calculate medical monitoring spending. *Id.* 254:13-17. Indeed, Dr. Song admits that, in addition to determining who should be in the class, multiple other factors will affect the quantities of services to be provided:

Q. So to apply your report to determine quantities, one would want to determine circumstances, such as insurance mix, life expectancy, and development of medical conditions, that may render the monitoring program less appropriate clinically. Right?

MR. MIGLIACCIO: Objection. Misstates.

A. Clinical appropriateness is a sort of sophisticated entity . . . I think the way you’re characterizing that here I would in some ways agree with, but I think it’s easier and more applicable to this case to say that life expectancy and the development of medical conditions may inform a factfinder or a decisionmaker at the end of the day regarding what medical services ought to belong in a monitoring program.

*Id.* 265:5-22. Dr. Song was unable to apply any of these factors because they are presently unknown. As a result, Dr. Song’s “common methodology” exists only in the abstract, consisting entirely of a fatally flawed assumption of healthcare pricing in the United States and a promise to compute quantity of services at some later date based on highly individualized inquiries into the circumstances of each class member’s medical care. *See id.* 268:10-269:2 (Q. “How about the issues of life

expectancy and medical conditions, how would we go about ascertaining that from the class members?” A. “Similarly, you could ask them about medical care that they’ve received before in the exercise that I was led through by your colleague counsel in earlier hours.”). Dr. Song’s purported “common methodology” is just “the beginning of a discussion” about the cost of the proposed medical monitoring “and not the end.” *UGI Sunbury LLC*, 949 F.3d at 835-36.

In short, as Dr. Song repeatedly concedes, he cannot apply his formula to calculate medical monitoring spending until after a class is ascertained and certified and the scope of services, mix of insurance, sites of care, and network status of the providers are defined. Even assuming it were possible to accomplish such an undertaking—and it is not—there would be no way to evaluate whether Dr. Song’s proffered “common methodology” is capable of calculating medical monitoring on a classwide basis until these data are somehow ascertained. As a result, Dr. Song’s opinion is not only based on a fundamentally unreliable pricing methodology, but also utterly disconnected from—and unhelpful to—the question of class certification.

## **CONCLUSION**

For the foregoing reasons, Dr. Song’s “common methodology” is unreliable, unhelpful, and should be excluded.

Dated: May 3, 2022

Respectfully Submitted:

By: /s/ Clem. C. Trischler

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 3, 2022, a copy of the foregoing document was served on all counsel of record via CM/ECF.

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